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Merck, Schering's Vytorin No Better Than Generic (Update4)

(Adds analyst comment in the 14th paragraph.)

By Michelle Fay Cortez and Shannon Pettypiece

Jan. 14 (Bloomberg) -- Merck & Co. and Schering-Plough Corp. said their cholesterol pill Vytorin worked no better than an older, cheaper drug, threatening the medicine's sales.

Vytorin combines Schering's Zetia and Merck & Co.'s Zocor, sold generically as simavastatin. Vytorin and Zetia, with $1.3 billion in third-quarter sales, may generate about 70 percent of Schering's profits in 2008, and 22 percent of Merck's, analysts have said. The findings spurred some doctors to say Vytorin should be used only if patients can't lower cholesterol using less expensive drugs, or those with more survival data.

The company-sponsored study examined the carotid arteries of 720 patients with a predisposition to high cholesterol who took the largest dose of Vytorin over two years. It found ``no statistically significant difference'' in plaque buildup between those on Vytorin or simavastatin, the companies said. A blocked carotid cuts blood supply to the brain, and can cause a stroke.

``We now need a moratorium on the use'' of Zetia and Vytorin, said Steven Nissen, head of cardiology at the Cleveland Clinic in Ohio, who wasn't involved in the study. ``In the absence of any evidence of a clinical benefit, these drugs should now be used as a last resort.''

Merck, based in Whitehouse Station, New Jersey, fell $1.29, or 2.1 percent, to $59.26 at 12:47 p.m. in New York Stock Exchange composite trading, after rising 31.8 percent in the year before today. Schering-Plough, of Kenilworth, New Jersey, dropped $1.87, or 6.7 percent, to $25.86.

## Zetia Performance

Zetia works in a different manner than drugs such as Zocor and Pfizer Inc.'s Lipitor, called statins. Zetia blocks the absorption of cholesterol in the digestive track while statins work by reducing production of cholesterol in the liver. No studies have yet shown Zetia or Vytorin is able to reduce the risk of heart attacks and strokes.

Merck and Schering-Plough have three additional studies on Vytorin under way involving more than 20,000 patients that may resolve those issues, the companies said. To get U.S. marketing approval, the companies needed only to show it lowered LDL, a standard measure for cholesterol drugs.

Investors have been concerned Schering-Plough won't be able to fend off competition to Zetia and Vytorin after sales of the drug missed analysts' expectations in the third quarter, sending shares down 13 percent, the most in more than six years.

## Mixed Results

The study provides mixed results on whether Vytorin will reduce heart attack and stroke risk more than simvastatin.

While Vytorin didn't reduce the thickness of the carotid artery more than simvastatin, it worked better at lowering the amount of LDL cholesterol in the blood, which can build up on

artery walls, the companies said today in a statement.

Schering-Plough spokesman Lee Davies said the Vytorin study wasn't definitive on whether the drug improves outcomes because it was looking at a rare population of patients with extremely high artery-clogging LDL cholesterol. Because patients had such high cholesterol levels, it may have been difficult to show a change in arterial thickness, he said.

``It was never intended to be a definitive study on outcomes,'' said Schering-Plough's Davies. ``They both started at incredibly high LDL levels so the patients were not brought to goal. If they were brought to goal, they might have had different outcomes.''

Merrill Lynch today downgraded its rating on Schering-Plough to ``neutral'' from ``buy'' on concerns the study findings will impact sales as doctors question the benefits.

`Further Pressure'

``We anticipate further pressure on Vytorin and Zetia prescription trends. We do not see Schering-Plough stock as a buy when the momentum of the key financial driver is uncertain,'' said David Risinger, a drug analyst with Merrill Lynch, in a note to clients today. ``We expect uncertainty about Vytorin and Zetia to weight on Schering-Plough's stock.''

Allen Taylor, chief of cardiology at Walter Reed Army Medical Center in Washington, D.C., said the findings suggest doctors should ``reconsider'' use of Vytorin.

``I think this provides no support for prescribing this drug at this point,'' he said.

The trial, called Enhance, found Vytorin and simvastatin had similar safety profiles, the companies reported. The results were submitted to the American College of Cardiology for presentation to a meeting in March.

The study also found a ``significant difference'' in so-called bad cholesterol among Vytorin patients and those on Zocor, with 58 percent reduction in Vytorin patients compared with 41 percent on Zocor, according to the company statement.

Rare Condition

Patients in the study had Familial Hypercholesterolemia, a rare condition that drives up cholesterol levels at an early age. At the start of the trial, patients in both groups had ``bad'' cholesterol levels that exceed 300 milligrams per deciliter, well above the 100 mg/dl that is considered optimal.

In November, Schering-Plough and Merck said they planned to change the main goal of the study because a review of the data was taking longer than expected. The decision to change the study, which the companies later reversed, spurred criticism from some doctors and caused investors to speculate that the findings would be unfavorable.

Prescriptions for Vytorin have been mostly unchanged this year after cheaper copies of generic Zocor came on the market in 2006. To combat the generics, Merck and Schering-Plough have spent $206 million advertising to consumers last year through September, according to Nielsen-Monitor Plus.

Simvastatin costs as little as three cents a pill, compared with $2.84 for the same dose of Vytorin and $2.63 for Zetia, said analyst John Boris, of Bear Stearns in New York, citing a

listing of the average wholesaler acquisition costs in a December note to clients.

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